

**BIOMET**  
CORPORATE HEADQUARTERS

**Summary of Safety and Effectiveness**

**Applicant or Sponsor:** Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

**Contact Person:** Michelle L. McKinley  
Regulatory Specialist

**Proprietary Name:** M2a™ Acetabular System

**Common or Usual Name:** acetabular cup prosthesis

**Classification Name:** prosthesis, hip, semi-constrained, metal/polymer, uncemented  
(888.3330)

**Device Product Code:** 87 KWA

**Substantially Equivalent Devices:** M2a™ Acetabular System, McKee Farrar, DePuy  
Pinnacle Metal-on-Metal Acetabular Cup Liners

**Device Description:**

*Acetabular Shell*

The 38mm M2a™ acetabular cup is cobalt chromium one-piece cup. The hemispherical shape of the acetabular cup closely matches the natural acetabulum, which leads to minimal bone removal in preparation for implantation. The inner surface of the cup is the bearing surface.

*Modular Femoral Head*

The 38mm M2a™ acetabular cup utilizes a 38mm cobalt-chromium (Co-Cr-Mo) modular femoral head. The modular heads may be used in conjunction with any of Biomet's commercially available Type I taper femoral components.

**Intended Use:**

The M2a™ Acetabular System is indicated for use in patients requiring total hip replacement due to the following:

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56 E. Bell Drive  
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- a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis
- b.) Rheumatoid arthritis
- c.) Correction of functional deformity
- d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
- e.) Revision of previously failed total hip arthroplasty.

**Basis of Substantial Equivalence:**

In terms of overall design and intended use, the M2a™ Acetabular System is equivalent to all other total hip acetabular components. Specifically, the geometry, materials, and fixation enhancements are similar to the following devices:

1. M2a™ Acetabular System: K993438, K003363
2. McKee Farrar: Pre-amendment Device
3. DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners: K003523

Mechanical testing was also used to determine substantial equivalence.

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